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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,008	08/11/2005	Mark A. Atkinson	36689.42	4535

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/512,008	ATKINSON ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10-14,16,17,19,20,24 and 32-47* is/are pending in the application.

4a) Of the above claim(s) *33-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10-14,16,17,19,20,24,32 and 43-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20041019,20041101,20070330*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 1, 10-14, 16, 17, 19, 20, 24, 32, and 43-47, in the reply filed on 3/30/07 is acknowledged.

Claims 33-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/30/07.

Specification

The disclosure is objected to because of the following informalities. The specification at page 27, line 3, fails to fully comply with 37 CFR 1.821(d), requiring that amino acid sequences be identified by their assigned SEQ ID NO. Since this sequence is part of a larger sequence, the amino acid sequence should be identified by the residue numbers in the assigned SEQ ID NO, e.g. --amino acids 47-50 of SEQ ID NO: 4--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11-13, 16, 17, 19, 20, 24, 32, 43, 44 are rejected under 35 U.S.C. 102(a) as being anticipated by Yamano et al. (J. Gene Med. 3: 450-457, 02 Aug. 2001), as evidenced by Muzyczka et al., US 6,020,192.

Yamano describes an AAV vector initially constructed by insertion of coding sequence for human IL-10 into *Not*I cleaved pTR-UF5, obtained from N. Muzyczka. Fig. 11 of Muzyczka et al. shows the structure of pTR-UF5. The resulting vector includes a CMV promoter, which has its own enhancer, and polyadenylation signal (a post-transcriptional regulatory signal). Yamano discloses virions and isolated human cells (293T) comprising the vector. See Yamano, page 451, col. 2, to page 452, col. 1.

With respect to claim 16, vectors having promoters that mediate expression in essentially all cells, e.g. a CMV promoter, meet this limitation. With respect to claim 32 to a kit, the presence of instructions does not constitute a limitation that distinguishes the kit from a prior art product lacking such instructions. *In re Ngai*, 70 USPQ2d 1862 (Fed. Cir. 2004).

Claims 1, 11-13, 16, 17, 19, 20, 24, 32, 43, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottard et al., (Gene Ther. 7: 1930-1939, 2000).

Cottard discloses an AAV vector comprising a CMV promoter, which includes the CMV enhancer, coding sequence for human IL-4 and a polyadenylation signal, which is a post-

transcriptional regulatory signal, as well as virions and isolated 293 cells (human) comprising the vector. See entire document, especially page 1935.

With respect to claim 16, vectors having promoters that mediate expression in essentially all cells, e.g. a CMV promoter, meet this limitation. With respect to claim 32 to a kit, the presence of instructions does not constitute a limitation that distinguishes the kit from a prior art product lacking such instructions. *In re Ngai*, 70 USPQ2d 1862 (Fed. Cir. 2004).

Claims 1, 11-13, 16, 17, 19, 20, 24, 32, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Flotte et al., WO 99/55564.

Flotte discloses AAV vectors and virions, and isolated mammalian cells comprising the vectors. The vectors comprise a promoter, e.g. β-actin promoter, with enhancer, e.g. CMV or myocyte-specific enhancer, linked to coding sequence for a cytokine, such as an interleukin, followed by a polyadenylation signal (post-transcriptional regulatory sequence). See entire document, especially page 2; page 7, line 25, to page 9, line 2; page 9, line 29, to page 10, line 2; and Fig. 1.

With respect to claim 16, vectors having promoters that mediate expression in essentially all cells, e.g. a CMV promoter, meet this limitation. With respect to claim 32 to a kit, the presence of instructions does not constitute a limitation that distinguishes the kit from a prior art product lacking such instructions. *In re Ngai*, 70 USPQ2d 1862 (Fed. Cir. 2004).

Claims 1, 10-14, 16, 17, 19, 20, 24, 32, and 43-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Loiler et al., US 2006/0292117.

The applied reference has a common inventor with the instant application, but not a common inventorship. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Loiler discloses AAV vectors comprising an expression cassette for producing a cytokine polypeptide, including IL-4, IL-10, IL10(I87A), in particular the human polypeptides. The promoter of the cassette may be a human β-actin promoter or a promoter comprising a CMV enhancer, a synthetic enhancer, a liver-specific enhancer, a lung-specific enhancer, a muscle-specific enhancer, a kidney-specific enhancer, a pancreas-specific enhancer, or an islet cell-specific enhancer. The cassette also comprises a post-transcriptional regulator signal, such as a polyadenylation signal and additionally a woodchuck hepatitis virus post-transcriptional regulatory element. Loiler discloses virions and isolated host cells containing the vectors, and kits containing the vector, virions, cells, or compositions thereof. See entire document, especially Figs. 7A and 13; paragraphs 0010, 0011, 0016, 0030-0032, 0035-0038, 0116, 0117, and 0120; and Table 1.

Claims 1, 11-14, 16, 17, 19, 20, 24, 32, and 43-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Hildinger et al., US 7,056,502.

Hildinger describes AAV vectors, and virions and isolated mammalian cells comprising the vectors. The AAV vectors comprise a promoter with enhancers, e.g. CMV promoter or β-

actin promoter, post-transcriptional regulatory sequences, such as a polyadenylation signal and woodchuck hepatitis virus post-transcriptional element, and coding sequence for a cytokine, such as IL-4 or IL-10. See entire document, especially cols. 2-3, 8-11, 15-16; col. 6, line 52, to col. 7, line 27.

With respect to claim 16, vectors having promoters that mediate expression in essentially all cells, e.g. a CMV promoter, meet this limitation. With respect to claim 32 to a kit, the presence of instructions does not constitute a limitation that distinguishes the kit from a prior art product lacking such instructions. *In re Ngai*, 70 USPQ2d 1862 (Fed. Cir. 2004).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hildinger et al., US 7,056,502, as applied to claims 1, 11-14, 16, 17, 19, 20, 24, 32, and 43-45 above, and further in view of Xiao et al., US 6,329,181.

Hildinger is described above. Hildinger teaches AAV vectors with a generic β-actin promoter, but not specifically a mammalian β-actin promoter.

However, Xiao describes AAV vectors generally, and particular methods of making them. It teaches a variety of promoters that can be used in AAV vectors, and specifically teaches that the human β-actin promoter is a ubiquitous, constitutive promoter suitable for use in AAV vectors (col. 15, lines 53-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the human β-actin promoter, taught by Xiao, as the β-actin promoter in the AAV vector of Hildinger, since Xiao taught that the human β-actin promoter was a suitable promoter for use in an AAV vector. See MPEP 2144.07.

Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hildinger et al., US 7,056,502, in view of Xiao et al., US 6,329,181, as applied to claims 1, 10-14, 16, 17, 19, 20, 24, 32, and 43-45 above, and further in view of PIR Acc. No. A25946 or PIR Acc. No. A38580.

Hildinger and Xiao are described above. Hildinger discloses that a primary use of the AAV vector is for delivery of the transgene carried in the vector to a human, such as in gene therapy (see Hildinger at col. 16, for example). Although Hildinger discloses an AAV vector

expressing IL-4 or IL-10, it does not teach that the sequences the IL-4 and IL-10 should be that of SEQ ID NOs: 1 (human IL-10) or 3 (human IL-4).

PIR Acc. No. A25946 or PIR Acc. No. A38580, which are disclosed in the instant specification on page 108 and assigned SEQ ID NOs: 3 and 1, respectively, show the sequences of human IL-4 and IL-10 were known in the prior art.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the AAV vector to have been made to express the human IL-4 or IL-10 shown in instant SEQ ID NOs: 1 or 3. Hildinger taught that one use of the AAV vector was for expression of the protein, such as IL-4 or IL-10, in a human, and the sequence for the human IL-4 and IL-10 was known. One of skill in the art of human gene therapy would understand that expression of the endogenous human protein would present fewer potential side effects than expression of an IL-4 or IL-10 from another organism.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633

Scott D. Priebe